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SARS-CoV-2USA-CA1/2020

CLIENT: JIBE LIGHTING

PROJECT: JIBE ION SURFACE TESTING

PRODUCT: JIBE AB-ION

CAP LIC NO: 886029801

CLIA LIC NO: O5D0955926

STATE ID: CLF 00324630

CHALLENGE VIRUS: SARS-CoV-2 USA-CA1/2020

INNOVATIVE BIOANALYSIS
creating solutions | getting results

ABSTRACT: EFFICACY OF THE JIBE LIGHTING AB-ION™ DEVICE AGAINST SARS-CoV-2

Background: This in vitro study was designed to determine the efficacy of the Jibe Lighting AB-ION™ unit. The product is a commercially available mobile disinfection device manufactured by Jibe Lighting Netherlands. The AB-ION™ unit is designed to be placed throughout a commercial or retail space and decrease the concentration of pathogens in the air and on surfaces when it is operating, in order to sanitize enclosed spaces and their contents. For this challenge, the SARS-CoV-2-CA1/2020 pathogen was used. Coronavirus can be spread through the air and by touching contaminated surfaces. There is a demand for disinfectant devices that have a proven ability to reduce infectious pathogens in the air thereby reducing the risk of human infection and transmission. Jibe Lighting supplied a pre-packaged AB-ION™ wall mountable unit for testing purposes. For the testing, power was supplied through a power regulated 120v outlet with surge protector and backup battery system. Test procedures were followed using internal SOPs for aerosolized viral pathogen challenges and subsequent decontamination. All internal SOPs and processes follow GCLP guidelines and recommendations.

Results: When tested against SARS-CoV-2-CA1/2020 virus, the Jibe Lighting AB-ION™ unit showed a reduction during the time it was operated resulting in a measurable loss. A single trial was conducted in a controlled environment. Two time points were selected as the base line sample collections points and after 15 minutes there was a 79% viral reduction. After 30 minutes of exposure the system showed it could reduce SARS-CoV-c-CA1/2020 on a surface by 99.99% compared to the control.

EQUIPMENT PROVIDED:

MANUFACTURER: JIBE LIGHTING

MODEL: AB-ION™

SERIAL #: N/A

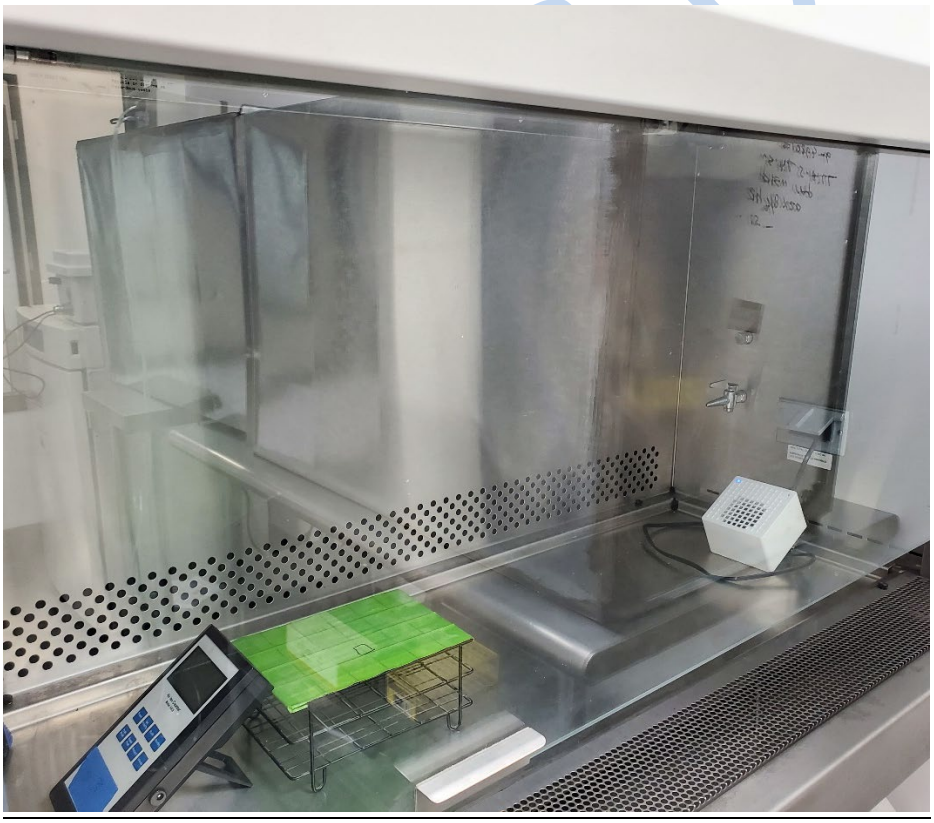
JIBE LIGHTING AB-ION™ EQUIPMENT:

The equipment arrived at the laboratory pre-packaged from the manufacturer and was inspected for damage upon arrival. The device was powered on to check for normal operations and confirm it could create positively and negatively charges ions.

VIRAL CHALLENGE TESTING CHAMBER:

A metal and glass bio safety chamber, 72”W x 30”H x 30”D with sealed seams was used for a surface testing site. The air temperature fluctuated slightly through the test and ranged from 70F to 71.F. During the control testing and the viral load tests the temperature fluctuation was consistent. The ambient humidity inside the test chamber was 39%. All seals for the chamber were confirmed and all equipment used had a function tests to confirm working conditions. For calibrated equipment, calibration records were checked to confirm operational status.

TESTING CHAMBER



EXPERIMENTAL SUMMARY:

- Prior to the initial control test and following each trial run the testing area was decontaminated and prepped per internal procedures.
- Temperature during all test runs was approximately 70F +/- 2F with a relative humidity of 39%.
- Directly next to samples there were two AIC2 Air Ion Counter continually logging the negative and positive ion counts.
- The AB-ION was placed on was side of the testing chamber with the glass slides for surface sampling on the opposite side.
- Ion concentration averages at the sample site were -82k per cm3
- Surface samples consisted of a 3" x 1.5" piece of sterile glass, 0.125" thick.
- Samples were taken at T-15 and T-30 minutes.
- For sample collection swabs were moistened with the viral suspension liquid and rubbed across the testing surfaces to pull as much standing viral media as possible.
- Swabs were sealed in individual tubular containers and stored in a sealed box for the duration of the test so no further ions could interact with them.
- Controls and viral challenge surface inoculation and sample collection were done in the same manner.
- During control testing average ion concentrations were -500 cm3.
- During control testing there was no airflow within the biosafety hood.

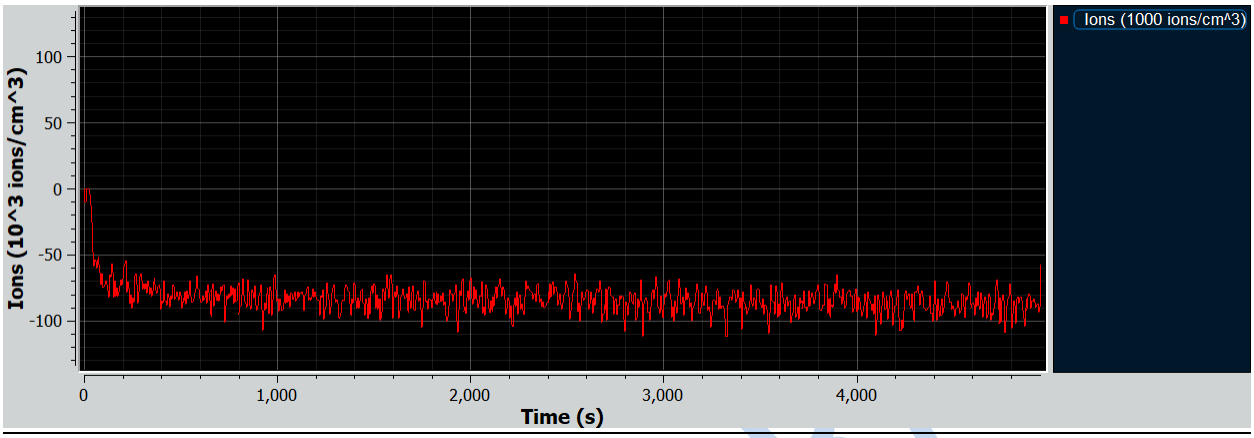
VIRUS STRAIN BACKGROUND:

The following reagent was deposited by the Centers for Disease Control and Prevention and obtained through the BEI Resources, BIAID, NIH SARS-Related Coronavirus 2, Isolate USA-CA1/2020, NR-52382. This was the chosen pathogen strain because it was taken from a 38-year-old subject with severe acute respiratory syndrome in California as was part of the A lineage.

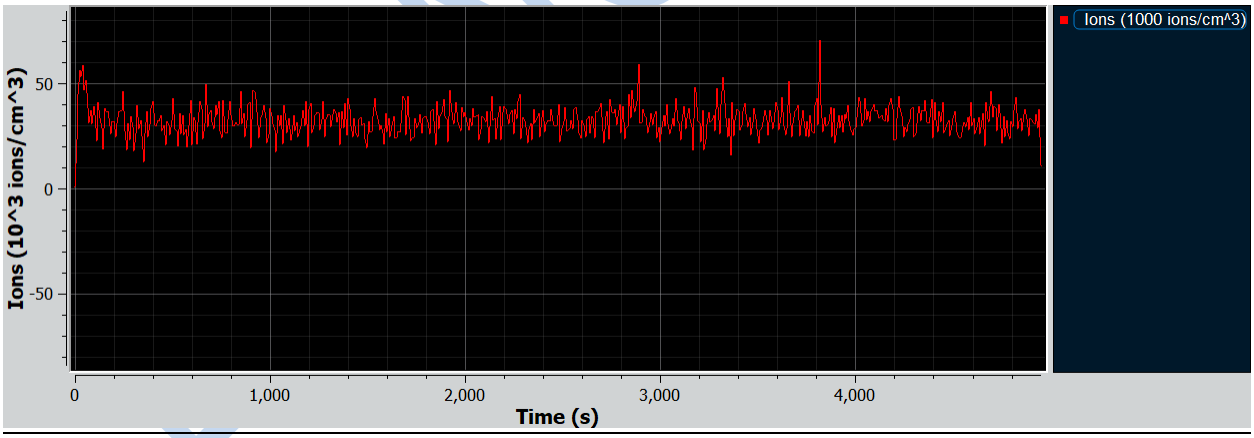
POST DECONTAMINATION:

At the conclusion of each viral challenge test the UV system inside the testing chamber was activated for 30 minutes. All test equipment was cleaned at the end of each day test with a 70% alcohol solution.

ION CONCENTRATION LEVELS AVERAGE -82K CM3



ION CONCENTRATION LEVELS AVERAGE +32K CM3



TCID50 PROCEDURE:

Materials and Equipment:

- Certified Biological Safety Cabinet
- Micropipette and sterile disposable aerosol resistant tips – 20uL, 200uL, 1000uL.
- Inverted Microscope
- Tubes for dilution
- Hemocytometer with cover slip
- Cell Media for infection
- Growth Media appropriate for cell line
- 0.4 % Trypan Blue Solution
- Lint Free Wipes saturated with 70% isopropyl alcohol
- CO_2 Incubator set at 37°C or 34°C or other temperature indicated.

Procedure:

1. One day prior to infection, prepare 96 well dishes by seeding each well with Vero E6 cells in DMEM plus 7.5 % fetal bovine serum, 4mM Glutamine, and antibiotics.
2. On the day of infection, make dilutions of virus sample in PBS.
3. Make a series of dilutions at 1:10 of the original virus sample. First tube with 2.0 mL PBS and subsequent tubes with 1.8mL
4. Vortex Viral samples, transfer 20 uL of virus to first tube, vortex, discard tip.
5. With new tip, serial dilute subsequent tips transferring 200 uL.

Additions of virus dilutions to cells

1. Label lid of 96 well dish by drawing grid lines to delineate quadruplicates and number each grid to correspond to the virus sample and label the rows of the plate for the dilution which will be plated.
2. Include 4 Negative wells on each plate which will not be infected.
3. Remove all but 0.1 mL of media from each well by vacuum aspiration.
4. Starting from the most dilute sample, add 0.1 mL of virus dilution to each of the quadruplicate wells for that dilution
5. Infect 4 wells per dilution, working backward.
6. Allow the virus to absorb to cells at 37°C for 2 hours.
7. After absorption, remove virus inoculum. Start with the most dilute and work backwards
8. Add 0.5 mL infection medium to each well being careful to not touch the wells with the pipette.

9. Place plates at 37°C and monitor CPE using the inverted microscope over a period of 1 to 4 weeks.
10. Record the number of positive and negative wells.

CONTROL:

One Control test was conducted without the AB-ION™ unit in the testing chamber. Control samples were taken at each of the corresponding sample times used for the viral challenge trial. Control testing was used for the comparative baseline to assess the viral reduction when the AB-ION™ device was operated in the challenge trial, to enable net reduction calculations to be made. An RKI O3 sensor was outfitted to the room and calibrated down to 1PPB accuracy to monitor O3 level during testing. During the control temperature and relative humidity were monitored. Prior to running the viral challenges temperature and humidity were confirmed to be in relative range to the control +/- 3%.

TESTING PROCEDURE:

TEST	SPECIFICATIONS	RESULTS
Identification by Infectivity in Vero 6 cells	Cell Rounding and Detachment	Cell Rounding and Detachment
Next Generation Sequencing (NGS) of complete genome using Illumina® iSeq™ 100 Platform (Approx. 940 Nucleotides	≥ 98% identity with SARS-CoV 2, isolate USA-CA1/2020 GenBank: MN994467.1 ≥ 98% identity with SARS-CoV 2, strain FDAARGOS_983 isolate USA-CA1/2020 GenBank: MT246667.1	99.9% identity with SARS-CoV 2, isolate USA-CA1/2020 GenBank: MN994467.1 100% identity with SARS-CoV 2, strain FDAARGOS_983 isolate USA-CA1/2020 GenBank: MT246667.1
Titer by TCID50 in Vero E6 Cells by Cytopathic effect	Report Results	2.8 X 10^5 TCID50 per mL in 5 days at 37°C and 5% CO2
Sterility (21-Day Incubation) Harpos HTYE Broth, aerobic Trypticase Soy Broth, aerobic Sabourad Broth, aerobic	 No Growth No Growth No Growth	 No Growth No Growth No Growth

Sheep Blood Agar, aerobic	No Growth	No Growth
Sheep Blood Agar, anaerobic	No Growth	No Growth
Thioglycollate Broth, anaerobic	No Growth	No Growth
DMEM with 10% FBS	No Growth	No Growth
Sterility (21-Day Incubation)		
Harpos HTYE Broth, aerobic	No Growth	No Growth
Trypticase Soy Broth, aerobic	No Growth	No Growth
Sabourad Broth, aerobic	No Growth	No Growth
Sheep Blood Agar, aerobic	No Growth	No Growth
Sheep Blood Agar, anaerobic	No Growth	No Growth
Thioglycollate Broth, anaerobic	No Growth	No Growth
DMEM with 10% FBS	No Growth	No Growth
Mycoplasma Contamination		
Agar and Broth Culture	None Detected	None Detected
DNA Detection by PCR of extracted Test Article nucleic acid.	None Detected	None Detected

VIRAL STOCK: SARS-CoV-2 USA-CA1/2020 (BEI NR-52382)

Inoculation of Surface Samples

Surface inoculation consisted of applying exactly 1 ml of viral media to each coupon with a calibrated Eppendorf pipette utilizing filtered pipette tips. Coupons were standard sterile 25mm x 75mm slides. Once applied, the media was spread thin using a disposable spatula and allowed to dry for 10 minutes. The starting concentration of virus that was applied was 4.53 X 10^6 TCID50/mL. After several tests for recovery, it was determined that the most efficient method of recovering viable virus would be a 2 mL rinse in viral media followed by a swab of the inoculated area.

Test Results: Surface Inoculation

Performed in the same manner as the control testing, the following deactivation rates were observed for direct surface inoculation in the challenge trial. Collection at each time point was done by swab and rinse of the coupon. Samples were collected by a technician at specified time from the bio safety container. The graph below represents the data for the experiment and the control, as it pertains to surface inoculation.

DISCLAIMER:

The Innovative BioAnalysis, LLC. ("Innovative BioAnalysis") laboratory is not certified or licensed by the United States Environmental Protection Agency and makes no equipment emissions claims pertaining to ozone or byproduct of any Jibe Lighting AB-ION™ device. Innovative BioAnalysis makes no claims to the overall efficacy of any AB-ION™. The experiment results are solely applicable to the device used in the trial. The results are only representative of the experiment design described in this report. Innovative BioAnalysis makes no claims as to the reproducibility of the experiment results given the possible variation of experiment results even with an identical test environment, viral strain, collection method, inoculation, viral media, cell type, and culture procedure. Innovative BioAnalysis makes no claims to third parties and takes no responsibility for any consequences arising out of the use of, or reliance on, the experiment results by third parties.

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